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1. **Background Information**

   The Kids Research Institute (KRI) is the “home” for all research conducted at The Children’s Hospital at Westmead (CHW). **The Australian Children’s Clinical Trials Centre (The ACCT Centre)** is a research enabler of the Kids Research Institute. The ACCT Centre, KRI and CHW are collocated with shared resources and staff.

   This information file refers to The Children’s Hospital at Westmead as the ‘site’.

   The Children’s Hospital at Westmead (CHW) is a full service academic hospital with over 300 registered beds and over 25,000 admissions per year. The Hospital is involved in caring for over 500,000 children and adolescents in NSW, which includes a third of the NSW aboriginal population and a growing refugee population.

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**Where is The ACCT Centre located?**

The ACCT Centre is housed within the Kids Research Institute at The Children’s Hospital at Westmead. The Hospital is located about 28 km west of Sydney city.

<table>
<thead>
<tr>
<th>Kids Research Institute</th>
<th>Mailing Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2, Cnr Hawkesbury Rd and Hainsworth St</td>
<td>Kids Research Institute</td>
</tr>
<tr>
<td>The Children’s Hospital at Westmead</td>
<td>Locked Bag 4001</td>
</tr>
<tr>
<td>Sydney NSW 2145</td>
<td>The Children’s Hospital at Westmead</td>
</tr>
<tr>
<td>Australia</td>
<td>Sydney NSW 2006</td>
</tr>
<tr>
<td>Phone 61-2-98451316</td>
<td>Australia</td>
</tr>
</tbody>
</table>

**Accreditation of the Hospital**

The hospital is accredited by the Australian Council on Healthcare Standards (ACHS) over a 4 year cycle. The program of accreditation used by the ACHS is based on a set of standards known as EQuIP (Evaluation and Quality Improvement Program). The ACHS is an independent, not for profit group whose members are private and public healthcare organisations.
Participant Population
Research groups recruit paediatric participants from the Greater Western Sydney area including wider NSW. Recruitment from outside of NSW may occur following specific permission from the CEO. The demographics of the patient population accessing The Children’s Hospital at Westmead within NSW include almost 50% born overseas:

<table>
<thead>
<tr>
<th>Birthplace</th>
<th>Sydney West</th>
<th>NSW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Born in Oceania and Antarctica (not Aust.)</td>
<td>3.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Born in North-West Europe</td>
<td>4.1</td>
<td>5.9</td>
</tr>
<tr>
<td>Born in Southern and Eastern Europe</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Born in North Africa and the Middle East</td>
<td>6.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Born in South-East Asia</td>
<td>6.8</td>
<td>3.5</td>
</tr>
<tr>
<td>Born in North-East Asia</td>
<td>8.2</td>
<td>3.4</td>
</tr>
<tr>
<td>Born in Southern and Central Asia</td>
<td>6.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Born in Americas</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Born in Sub-Saharan Africa</td>
<td>1.3</td>
<td>0.9</td>
</tr>
<tr>
<td>Total born overseas</td>
<td>42.6</td>
<td>25.5</td>
</tr>
</tbody>
</table>

How many clinical research studies are conducted at CHW?
The Children’s Hospital at Westmead Ethics Committee approves approximately 50 clinical research studies each year to be conducted at this site. The majority are submitted from resident clinical researchers but increasing numbers have been Pharmaceutical industry-sponsored clinical trials.

Significant Research Achievements
Total competitive grant funding for KRI was over $12.5 milion for 2009

- Opening of the first NSW facility for human cellular and gene therapy applications.
- Institute of Endocrinology and Diabetes is internationally recognised for its expertise in type 1 diabetes research into the prevention of complications, reducing the incidence of diabetes in the genetically at risk and attempting to reverse metabolic abnormalities and prevent development of diabetes. It is also leading the way in the assessment of Vitamin D therapy for Rickets.
- First cancer gene therapy trial targeting bone marrow stem cells in Australia.
- Identification of a common genetic variant that influences muscle performance in elite athletes and the general population.
- The Children’s Hospital Burns Research Institute pioneered the use of Laser Doppler Imaging to predict burn wound outcome. New equipment has now been developed to complete the process in 5 seconds rather than 3 minutes.
Significant Research Achievements continued

• The Institute of Neuroscience and Muscle Research (INMR) is conducting the first clinical trial in Australia of a new medication for children with Duchenne Muscular Dystrophy.

• First randomised trial of inpatient weight restoration versus brief hospitalisation for management of anorexia nervosa.

• PRIVENT was the world’s largest study investigating if long-term antibiotics prevent urinary tract infections in children. This clinical trial is now complete and concluded that long-term antibiotic use was associated with a decreased number of urinary tract infections in predisposed children.

• National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS) has been instrumental in improving the immunisation rates of all Australians. Influenza is currently a priority. Most recently, a H1N1 09 “swine” influenza vaccine immunogenicity trial was conducted. Pertussis is also a focus and a study has commenced assessing monovalent pertussis vaccine administered at birth.

• Discovery of new treatments to promote bone healing. In a world first the Orthopaedic Research and Biotechnology Unit has demonstrated that cells from the surrounding muscle make a key contribution to bone formation and repair in serious skeletal injury.

• The Genetic Metabolic Disorders Research Unit discovered the gene responsible for Arts Syndrome allowing the implementation of a new therapy.

• The Children’s Hospital Education Research Institute (CHERI) is involved in an international clinical trial to determine whether a cholesterol lowering medication reverses learning problems in children with neurofibromatosis type 1.

• The Children’s Chest Research Centre has been involved in assessing the use of a new inhaled therapy as a diagnostic test for children with asthma and also as a treatment for children with cystic fibrosis. It has also evaluated formulations of antibiotics developed specifically for children with cystic fibrosis and is consistently involved in studies in children with asthma.
2. Research Ethics and Governance

Prior to commencing a clinical trial the protocol must be reviewed by a Human Research Ethics Committee (HREC). Clinical trials are only authorised to begin once they have both Ethics and Governance approval. Prior approval/acknowledgement by the Therapeutic Goods Association (TGA) to conduct a clinical trial is also required for some high risk trials.

Is ethical approval accepted from an interstate or overseas HREC?
Currently No.
However, with the HoMER Review it may be possible to accept ethical approval from interstate ethics committees in the future.

Can approval for a multi-centre study be provided by any NSW HREC?
No – in NSW, under the single ethical review system, only a lead HREC can provide single ethical approval for multi-centre studies.

Is the HREC at CHW a lead ethics committee?
Yes – The Children’s Hospital at Westmead HREC is a lead ethics committee for NSW Health with expertise in paediatric clinical research. A full-time Ethics Manager oversees this undertaking.

What is the name of the Ethics committee at CHW?
Royal Alexandra Hospital for Children Ethics Committee (Reference: EC00130).

Are there standard ethics and governance approval application forms?
Yes – the National Ethics Application Form (NEAF) and Site Specific Application Form (SSAF) are accessible online http://www.ethicsform.org/au.

What are the fees for an ethics and governance submission?

Are pharmacy / other local fees included in ethics and governance fees?
No – pharmacy fees must be negotiated and signed off with the Clinical Trial Pharmacist prior to submitting the Site Specific Application (SSA). Service fees from other departments (e.g., Medical Imaging, Pathology) must also be negotiated prior to SSA submission.

How is governance approval obtained?
The hospital still retains responsibility for authorising the commencement of research to be undertaken at the site and requires the Site Specific Assessment Form (SSAF) to be completed for each research project to assess the capacity to conduct the research.
Where is the SSAF obtained?
The SSAF will be partially, automatically populated when the NEAF is completed. The SSAF is accessed from the same online site as the NEAF. Assistance for completion can be sought from the Research Governance Manager.

When is the SSAF submitted?
Preferably in conjunction with the ethics application to the CHW HREC but can be submitted separately.

Adverse Event Reporting Requirements
Investigators are required to comply with the NHMRC Australian Health Ethics Committee May 2009 Position Statement on ‘Monitoring and reporting of safety for clinical trials involving therapeutic products’ and The Children’s Hospital at Westmead local policy on Adverse Event Reporting in Clinical Trials. The Principal Investigator (PI) is able to access the local policy, timeframes and forms from the CHW Ethics Intranet Site.

A Serious Adverse Event (SAE) or a Serious Unexpected Suspected Adverse Reaction (SUSAR) occurring at this site or a site under CHW HREC approval requires reporting as soon as possible to the CHW HREC using an individual adverse event form. The CHW HREC requires annual SAE summary reports and six-monthly SUSAR summary reports.

Information Required for Clinical Trial Agreements


Legal name of Institution (CHW): The Sydney Children’s Hospital Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)

ABN: 53 188 579 090

Signatory on behalf of Institution: Chief Executive

Certificate of Insurance: The position of CHW is that the Clinical Trial must be listed on the certificate and be current. It must also be in Australian dollars.

Standard Form of Indemnity: the study sponsor is also required to complete a Standard Form of Indemnity in favour of the institution and this is to be inserted at Schedule 3 of the CTA. The Standard Form of Indemnity is available at: [http://www.medicinesaustralia.com.au/pages/page39.asp](http://www.medicinesaustralia.com.au/pages/page39.asp).
**TGA documents:** In Australia there are two main routes for conducting a clinical trial of a new therapeutic good or new uses of therapeutic goods; the Clinical Trial Exemption (CTX) Scheme and the Clinical Trial Notification (CTN) Scheme. The CTX Scheme is an approval process and the CTN Scheme is a notification process. Over 95% of all trials conducted in Australia obtain regulatory approval via the CTN scheme.

Prior to SSAF submission the CTN must be signed by the investigator and all sections completed except for “Sponsor Signature”. If you are conducting a sponsored clinical trial, the CTN form is the responsibility of the sponsor and it is a requirement that they sign it last to note that it has been completed correctly by all parties prior to sending it to the TGA. Therefore, the sponsor is not required to sign it prior to SSAF submission.

**What timeframe may be expected from application to approval?**
At CHW, the ethics and governance approval process takes a minimum of 6 weeks following submission of the NEAF and SSAF. The TGA CTN system is immediate following notification but the CTX approval system is on a 50 day clock.

**Has the CHW, as a site, been audited by an independent auditor?**
Yes - feedback is available on request where applicable

**Is there a need to translate patient information sheets and consent forms into other languages?**
No – not generally, as interpreters are available to be present while obtaining consent. However, if the study population has significant Cultural and Linguistically Diverse characteristics, then translation services are available for this purpose through hospital-approved vendors.
3. Research Streams and Staff Expertise

What kind of research is conducted at CHW?

- Laboratory
- Clinical / Translational
- Drug studies
- Medical Device studies
- Pharmacogenomic studies
- Population Health
- Diet and Exercise studies
- Vaccine studies
- Sponsored and Investigator-driven studies
- Phase I and proof of concept clinical trials

What Departments are involved in Research at CHW?

Stream 1 – Neurosciences and mental health
- Institute of Neuroscience and Muscle Research
- Department of Adolescent Medicine and Eating Disorders
- Children’s Hospital Education Research Institute (CHERI)
- Developmental Cognitive Neuropsychology Research Unit (DeCog)

Stream 2 – Tissue engineering and Bone Repair
- Orthopaedic Research and Biotechnology Unit
- Children’s Hospital Burns Research Institute (Clinical - CHBRI)
- Wound Healing Laboratory

Stream 3 – Cancer biology
- Children's Cancer Research Unit

Stream 4 – Genetics, gene therapy and genomics
- Western Sydney Genetics Research Program
- Gene Therapy Research Unit (GTRU)

Stream 5 – Obesity, metabolism and nutrition
- Institute of Endocrinology and Diabetes
- Obesity Research Group
- Children’s Hospital Institute of Sports Medicine (CHISM)
- The James Fairfax Institute Research Group

Stream 6 – Renal medicine and Transplantation
- Centre for Kidney Research (CKR – clinical and laboratory)

Stream 7 - Infectious disease, immunology
- Centre for Perinatal Infection Research
- National Centre for Immunisation Research and Surveillance (NCIRS)
- Department of Allergy and Immunology
- Department of Infectious Diseases and Microbiology

Stream 8 – Clinical sciences and health services delivery
- Australian Paediatric Surveillance Unit (APSU)
- Centre for Trauma Care, Prevention, Education and Research
- Division of Allied Health
- Respiratory Medicine Research (Children’s Chest Research Centre)
- SIDS and Sleep Apnea Research
- Neonatology and the Grace Centre for Newborn Care Research Unit
- Department of Nuclear Medicine
- Nursing Research and Practice Development Unit
- Kids Critical Care Research
- Centre for Evidence Based Paediatrics, Gastroenterology and Nutrition (CEBPGAN)
- Rehabilitation Research
- Kids Heart Research

How many potential investigators / study coordinators?
There are over 300 researchers and clinicians involved in medical research across the range of disciplines with Principal Investigators and Study Coordinators facilitated based on study need.

**Will the PI & study coordinator be able to attend investigator meeting?**
Yes – with prior notice and depending on location and availability

**Will the PI & study coordinator be able to meet with the CRA for monitoring?**
Yes – with prior notice and depending on availability

**Can study coordinators conduct home visits?**
Yes – although CHW has Policy Guidelines that staff are required to follow

**How many studies do coordinators conduct at a time?**
This is dependant on complexity of the study and number of patients participating

**Are there qualified staff to obtain samples eg blood, sputum & prepare them for transport?**
Yes, there are staff trained in IATA requirements. There are also Research Scientists who have experience in the generation of biological reagents suitable for clinical use, such as retroviral vector supernatant for gene therapy applications. In addition, there are staff experienced in the manipulation of patient cells for clinical use (transplantation).
4. Facilities / Capabilities / Equipment

The Westmead research “hub” is one of the largest health and medical research campus in the southern hemisphere and collaboration occurs across the campus.

The hub includes The Children’s Hospital at Westmead (CHW), Westmead Adults Hospital, Kids Research Institute (KRI), the Children’s Medical Research Institute (CMRI) and the Westmead Millennium Institute (WMI).

Further information on services provided and resources available can be obtained from the following links: http://www.chw.edu.au/prof/services/ and http://www.chw.edu.au/research/hub/

What genomic science technologies are available?
Microarray scanner, DNA sequencer, Real time thermocycler

What protein science technologies are available?
Mass spectrometry, protein analysis (Biocore) and automated chromatography (Biocad).

What microscopic technologies are available?
Optical and fluorescence microscopy, Confocal microscopy, Live cell imaging, Laser Capture Micro-dissection Microscopy and electron microscopy.

Are there onsite laboratory facilities?
Yes
Accredited pathology, medical imaging, ultrasound, neuromuscular, sleep, cardiac and respiratory function laboratories are available and use is facilitated based on study requirements

A Bio-bank and Pathology Support Laboratory exists.

A Human Applications Laboratory (HAL), the Westfield Gene and Cell Medicine Facility, has been commissioned and is used for the production of clinical-grade vector supernatant to be used in a gene therapy clinical trial. The facility consists of 2 clean-room tissue culture labs and a Contained Clean lab linked to the central Workroom by airlocks. Air quality in each room meets C, B or D Class standards, respectively, with Class A air provided by Laminar Flow Biohazard Hoods in each of the labs. Air cleanliness is maintained by HEPA filtered air flow across pressure gradients.

A Human Movement Laboratory is a research space for assessing the gait, performance and physiology of children before, during and after clinical trial intervention. It houses state-of-the-art kinetic/kinematic outcome equipment and multiple cameras for instrumented gait analysis, strength measurement and balance assessment.
Are specimen storage freezers available and are they monitored and alarmed?
Yes, although discussions with individual research units and the laboratory manager will determine availability of storage freezers.

All -80° freezers are connected to the building monitoring system and go into alarm when the temperature rises above -65° degrees. The daily temperatures are not monitored. It is possible to purchase a data logger if daily monitoring is required following negotiations with individual units and the laboratory manager.

There are a number of -20° freezers but only one is monitored.

Are there onsite investigational pharmacies with locked / temperature monitored storage?
Yes – A designated Clinical Trials Pharmacist is available. A dedicated storage area for clinical trials pharmaceuticals exists. This is monitored for environmental parameters such as temperature and is overseen by a building monitoring system.

Are hospital beds available?
No.
Participants in research studies are not permitted to be allocated a hospital bed as part of the study. Turner Ward is available for research purposes. Turner Ward is a unique hospital ward consisting of a Medical Day Stay Unit, a Care by Parent Unit and an Endocrine Testing Unit with two treatment rooms, two day rooms and a small laboratory. The unit currently hosts clinical and research activities.

In the event of a disease exacerbation or unexpected adverse event occurring that requires hospital admission normal hospital protocol will be followed.

Is there designated clinical research space?
Yes
There are four consultation rooms within the main Hospital building dedicated to clinical research. These rooms have beds and basic equipment required for initial and follow-up consultations with trial participants.

The Kids Research Institute has one large conference room, three meeting rooms and 5 call centre rooms.

Is internet / phone access available for monitoring visits?
Yes
5. Computer / Internet Capabilities

Functionality

Vendor / System name

System Owner

Is there trial data (efficacy or primary safety) collected in the system that has no other source?

What other applications are available via the electronic medical record?

Is the electronic medical record, and all applications available through it, validated in the hospital environment?

Electronic Medical Record Capabilities

Are there IDs and passwords to access the system?

Are passwords kept confidential (not shared)?

Does the system automatically log off a user after a specified period of inactivity?

Is access to certain functions controlled based upon the user’s role (e.g., read, write, change, delete)?

Is there an audit trail for capturing changes to information in the system?

Is the audit trail system-generated (does not require the user to create an audit trail record)?

Electronic Medical Record

Cerner / PowerChart

The Sydney Children’s Hospital Network (Randwick and Westmead) (incorporating The Royal Alexandra Hospital for Children)

All paper documentation is scanned into an imaging system and available directly through the electronic medical record system.

Health e-care

Critical Care Information System

Medical Imaging

PAX

RIS

OpenText

Yes; signed documentation is available on request

Yes

Yes

Yes

Yes

Yes
Is the original information as well as the new information still available after the change is made? (Attach example if appropriate)  Yes

Are the audit trail entries date- and time-stamped? Yes

Does the audit trail indicate who made a change? Yes

Is the audit trail protected from modification by users? Yes

Is the audit trail protected from being turned off? Yes

Is the data in the system backed up (either via a network connection or onto diskette or tape, for example) in case of system failure or loss of data? Yes

How frequently is this done? Nightly image backup via network connection

Can this backed up data be restored? Yes

Has the restoration of backup data been tested? Yes - In the test environment

Are electronic signatures used in the system? No

How will the CRA access the data for monitoring? Read only access using specific research logon account

Is the system capable of restricting the CRA’s access to ONLY those patient records of trial subjects? Yes - Medical records add patients to a restricted list for access by research account

How much notice is required to gain access? 2 – 4 weeks.
This includes application to IT for account and password and time for Medical Records to create participant list.
6. Recruitment Strategies

Depending on the recruitment needs of the study, a participant recruitment plan is customised. This is designed in consultation with the Ethics Committee:

- CHW emergency admissions database, outpatient and satellite clinics and community-based practice referrals
- Advertising – radio, television, newspaper (daily and community) as well as special interest magazines such as “Sydney’s Child”
- CHW publications including print and electronic newsletters, magazines and other publications
- Database recruitment
- Email – using CHW internal email system to 3000 employees
- Grand Rounds presentations and other speaking opportunities within CHW and in the community
- Internet and intranet

7. Staff Contacts

The Australian Children’s Clinical Trials Centre
Project Coordinator: Dr Kimberley Lilischkis
kimberll@chw.edu.au

Assistant Project Coordinator: Dr Lucia Smith
lucias@chw.edu.au

Clinical Trials Pharmacist: Pathma Joseph
pathmam@chw.edu.au

Kids Research Institute
Laboratory Manager: Matt Laver
matthel1@chw.edu.au

The Children’s Hospital at Westmead
Ethics Manager: Karen Steinhoff
karens10@chw.edu.au

Governance Manager (F/T): James Cokayne
jamesc5@chw.edu.au

Governance Manager (P/T): Carolyn Casey
Carolyb3@chw.edu.au